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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,335	10/09/2001	Barbara A. Soltz	P00594-US	6202

3017 7590 08/17/2004

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EXAMINER	
PANTUCK, BRADFORD C	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 08/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/973,335	SOLTZ ET AL.	
	Examiner	Art Unit	
	Bradford C Pantuck	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02-24-2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-3, 5, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,310,036 B1 to Browdie in view of U.S. Patent No. 5,209,776 to Bass et al. Regarding Claims 1-3, 6, and 8, Browdie discloses bonding tissues together [Column 1, lines 8-15]. Browdie continue mentions that his substances are adhesives for application to tissue. Browdie discloses the claimed concentration of collagen: in Column 6, lines 15-18 the solution is said to have 35% to 45% concentration of collagen. These percentages translate into 350 mg/mL to 450 mg/mL because a concentration is, by definition, in units mass per unit volume. Applicant defines "gelatinization" very broadly from pages 6-7 of the specification as forming something into a viscous liquid, gel, or solid. Browdie speaks throughout the patent of how well known it is to gelatinize the kinds of substances he is talking about, and although he does not specifically say that his substance is gelatinized, he does say that he uses "cold lyophilization" [Column 6, lines 15-17] to make his solution more concentrate, which Examiner asserts would make his substance fit into the broad limitation of being a liquid, solid, or a gel.

Regarding being derivatized with a COO- or a SH- functional group, Browdie does not say verbatim that he is causing COO- molecules to bond with his collagen molecules. However, *Browdie discloses the same process as the Applicant's for treating his collagen*, and would therefore have the same outcome as the Applicant. Browdie discloses adding glutamate and glutaraldehyde solutions to the collagen [Column 5 line 65 to Column 6 line 1]. Browdie refers to the alcohols he is using as "cross-linking agents," implying that they are used for helping to create covalent bonds between the collagen and free ions of some sort.

Comparing to Applicant's specification at page 9 3rd and 4th paragraphs, it is clear that "for derivatization to attach SH- and COO- groups" [Specification, page 9 first line of 3rd para.] *all that is needed is mixing the collagen with well-known kinds of alcohol.*

The burden is shifted to the Applicant to show that Browdie's reaction will not add COO- molecules to the collagen. It is suggested that Applicant uses chemical formulas showing the chemical formulas of collagen, alcohol and how the acid-base reaction works. *Why would Browdie's reaction not cause a derivatization when his process is the substantially the same as Applicant's*?

Within Browdie's patent it is recognized that various procedures for adding heat to the adhesive are well known. In Column 4, lines 3-34 Browdie cites lasers and high frequency energy as well-known ways to help weld tissues together. Bass teaches that using a laser in conjunction with an adhesive has advantages over the use of one or the other separately: specifically in Column 3 lines 1-7, Bass teaches that

using a laser with an adhesive both reduces trauma to the wound and increases weld strength. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use a laser (or other energy in the electromagnetic or infrared spectra) [Column 5, lines 6-16; Column 9 lines 41-42] with the adhesive of Browdie in order to have a stronger and faster healing wound closure, as taught by Bass.

2. Regarding Claim 5, Bass discloses using cyanoacrylate along with his adhesive [Column 2, lines 12-20].

3. Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,310,036 B1 to Browdie in view of U.S. Patent No. 5,209,776 to Bass et al. in further view of U.S. Patent No. 5,713,891 to Poppas. In Column 7, lines 17-23, Poppas discloses using a temperature sensing means along with a laser so as to avoid excessive heating, which could damage the body tissue. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to monitor the temperature of the surface of the adhesive and adjust it accordingly in order to avoid damaging body tissue, as taught by Poppas. Additionally at the time of the invention, it would have been obvious to one of ordinary skill in the art to us the laser to weld the collagen at a temperature of 55- 60 degrees Celsius since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaver or McDermott can be reached on (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP
August 6, 2004

DAVID O. REIP
PRIMARY EXAMINER